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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,812	09/11/2001	Wolfgang Podszun	MO/6546/LEA33.254	4401

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EXAMINER

HASHEMI, SHAR S

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/13/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,812

Applicant(s)

PODSZUN ET AL.

Examiner

Shar Hashemi

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 13 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input checked="" type="checkbox"/> Other: <i>Structure Report</i> . |

DETAILED ACTION

Specification

1. The use of the trademarks "Eppendorf" (page 17, lines 10 & 29), "BIO-RAD" (page 18, line 3) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.

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(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 18, line 3). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14-19 & 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 14-16, 18, and 23 are indefinite because the acronym "BET" is confusing. It is unclear as to whether the acronym "BET method" corresponds to the Brunauer-Emmett-Teller method or another method. At page 6, line 1, the specification discloses the acronym "BET" but does not provide a definition for the acronym. Amending the claims and specification to include a definition for the acronym "BET" would obviate the rejection.

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B) Claims 14-15, 17, 19 & 23 are indefinite because the phrase “swell in water” or “swellable in water” is confusing. Based upon the limitation “swell in water” or “swellable in water,” it is unclear as to whether the claimed water-insoluble polymer possesses a highly absorbent property or poorly absorbent property. At page 13, lines 9-29, the specification discloses the term “swelling” but does not provide an adequate definition for the term “swelling.” Amending the claims or specification to include a definition for the term “swell” would obviate this rejection.

C) Claim 14 is indefinite because the term “hydrophilic” in claim 14 at page 3, line 3 is confusing. Claim 14 recites a method for isolating nucleic acids from a sample utilizing a bead polymer composed of a vinyl monomer that is both hydrophobic (page 2, step c1) or hydrophilic (page 2, substep c2). It is unclear as to whether the recited vinyl monomer is hydrophobic or hydrophilic. Amending the claim to clarify polymer’s affinity for water would obviate the rejection.

D) Claim 23 is indefinite because the term “hydrophilic” in claim 23 at page 5, substep c2 is confusing. Claim 23 recites a composition for isolating nucleic acids from a sample utilizing a bead polymer composed of a vinyl monomer that is both hydrophobic (page 5, step c1) or hydrophilic (page 2, substep c2). It is unclear as to whether the recited vinyl monomer is hydrophobic or hydrophilic. Amending the claim to clarify polymer’s affinity for water would obviate the rejection.

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 12-13 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Karlou-Eyrisch et al (US 2002/0106659 A1).

Karlou-Eyrisch et al teach a bead polymer and a method for isolating nucleic acids from a sample containing nucleic acids comprising:

a) mixing at a pH of 7 or less the sample with a water-insoluble polymer that is not ionic in the basic and neutral range, where the polymer is a bead having an average particle size of from 3 to 100 um and consists of polymerized units of 1) 5 to 98% by weight of amino monomer 2) 0.3 to 30% by weight of crosslinker and 3) 0 to 93% by weight of vinyl monomer thereby absorbing the nucleic acids (pages 1 par. 12 to page 4 par. 49),

b) separating the water-insoluble polymer on which is absorbed the nucleic acids,

c) mixing the water-insoluble polymer with an aqueous phase with a pH of greater than 7, thereby liberating the adsorbed nucleic acids (page 3, par. 43).

They further teach the sample is a biological material that is lysed after the mixing step (page 3, par. 45)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonn et al (WO 94/11305 May 26, 1994) in view of Noetzel et al (US 4,568,706 February 4, 1986).

Bonn et al teach a bead polymer and method for isolating nucleic acids from a sample containing nucleic acids comprising:

a) mixing at a pH of 7 or less the sample with a water-insoluble polymer that is not ionic in the basic and neutral range, where the polymer is a bead having an average particle size of from 3 to 100 μm and a specific surface area measured by the BET method of from 5 to 500 m^2/g and consists of polymerized units of 1) 5 to 98% by weight of amino monomer 2) 0.3 to 30% by weight of crosslinker and 3) 0 to 93% by weight of hydrophobic or hydrophilic vinyl monomer or a bead polymer that is able to swell in water well having an average particle size of from 3 to 100 μm (see whole document, especially page 4 par. 5 to page 14 par.3),

b) separating the water-insoluble polymer on which is absorbed the nucleic acids (page 17, par. 4-5),

c) mixing the water-insoluble polymer with an aqueous phase with a pH of greater than 7, thereby liberating the adsorbed nucleic acids (page 17, par. 4-5).

They further teach the sample is a biological material that is lysed after the mixing step (page 10, par. 3). They also disclose a method for preparing bead polymers having an average particle size

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of from 3 to 100 μm and a specific surface area measured by the BET method (page 9, par. 3) of from 5 to 500 m^2/g comprising (page 11 par 2 to page 16 par.3) :

a) dispersing in an aqueous medium using a protective colloid a mixture of 1) 5 to 98 parts by weight of amino monomer 2) 2 to 30 parts by weight of crosslinker 3) 0 to 93 parts by weight of hydrophobic or hydrophilic vinyl monomer 4) 10 to 150 parts by weight of porogen 5) 0.1 to 2.5 parts by weight of free-radical former (page 12 par. 4 to page 14 par. 3),

b) polymerizing the resulting dispersion by heating to the decomposition temperature of the free-radical former (page 14, par. 1-3), and

c) removing the porogen by extraction and/or evaporation (page 8, par. 2-3).

They disclosed the amino monomer is similar to compound of formula (I) (page 8, par. 1-3; see attached structure report). They teach the method for preparing the amino monomer comprising reacting 2-isocyanatoethyl methacrylate with 3-aminopropylimidazole (page 8 par. 2 to page 9 par 2).

Bonn et al do not teach pore diameter of from 10 to 1,000 nm.

Noetzel et al teach macroporous bead polymers and a method for preparing and using, where the pore diameter is 10 to 1,000 nm (col. 5, lines 53-67).

One of ordinary skill at the time the invention was made would have been motivated to apply Noetzel et al's pore diameter of 10 to 1,000 nm to Bonn et al's bead polymer and a method for preparing and using in nucleic acid isolation in order to be employed in chromatographic processes (col. 6, lines 11-23). It would have been prima facie obvious to apply Noetzel et al's pore diameter of 10 to 1,000 nm to Bonn et al's bead polymer and a method for preparing and using in nucleic acid isolation in order to be employed in chromatographic processes.

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An ordinary practitioner would have recognized that the results optimizable variables of components, product amount and individual concentrations could be adjusted to maximize the desired results. As noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of components and individual concentrations for the polymerized units was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Furthermore, as noted in *In re Levin*, 84 USPQ 232,

Nothing critical is seen in the proportions as specified in certain of the claims and nothing unusual appears in the compounding procedure. The respective tribunals of the Patent Office reached the final and concurring conclusion that, in view of the art of record, appellant had merely associated well-known ingredients in a unitary composition, with no new or unexpected cooperative relationship between them.

SUMMARY

9. No claims allowed.

CONCLUSION

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee

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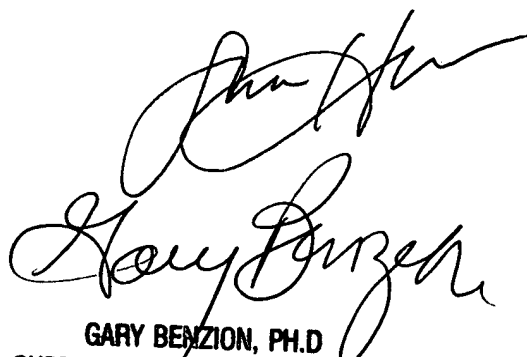
security through the e-mail system nor should official papers be transmitted through this route.

The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703) 305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

January 27, 2003



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